K092526

PARI Sinus
510(k) Submission
510(k) Summary

MAY - 6 2010

Submitter Information

Name:	PARI Respiratory Eqiupment, Inc.
Address:	2943 Oak Lake Blvd. Midlothian, VA 23112
Phone Number:	804-253-7274 x269
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Contact Name:	Michael Judge
Date Prepared:	August 18, 2009

Device Name

Common Name:	Nebulizer
Trade Name:	PARI Sinus
Classification Name:	Nebulizer (Direct Patient Interface), §868.5630, Product Code CAF

Legally Marketed Predicate Device(s)

Manufacturer	Device	510(k) Number
PARI Respiratory Equipment, Inc.	LC Star with Nasal Adapter	K061381
DHD Healthcare Corp.	Acapella	K002768
PARI Respiratory Equipment, Inc.	Proneb Ultra	K002862
PARI Respiratory Equipment, Inc.	LC Sprint	K060399

Device Description

The PARI Sinus is a single patient use, reusable aerosol therapy device for delivery of prescribed medications to the upper airway. The device is non-sterile, prescription-use only, intended for use in hospital, clinic, or home environments. The PARI Sinus utilizes a combination of aerosol flow and vibration to effectively deliver aerosolized medications to the upper airway.

Indications For Use

The PARI Sinus is a compressor nebulizer system, designed to aerosolize medication approved for nebulization and prescribed by a physician for delivery to the upper airways. The PARI Sinus is intended for adult and pediatric patients consistent with the indications for aerosol medication, in homes, hospitals, and sub-acute institutions.

Technological Characteristics Compared to Predicate Devices

The PARI Sinus, LC Sprint, and LC Star with Nasal Adapter are reusable, air compressor-driven jet nebulizers which use the same method of aerosolization. The PARI Sinus compressor and the Proneb Ultra compressor are both piston-driven, oil-less air compressors powered by shaded pole AC motors, and produce comparable operating pressure. The PARI Sinus system and the Acapella predicate both generate comparable low-amplitude vibrating pressure which is applied to the upper airways.

The PARI Sinus uses drug/air path materials that are similar to the predicate LC Sprint device.

Non-Clinical Test Summary

PARI Sinus was tested to compare performance to the predicate devices, including:

- MMAD: PARI Sinus is comparable to the predicate devices.
- Total Mass: PARI Sinus is comparable to the predicate devices
- Vibrating pressure amplitude: PARI Sinus is comparable to the predicate devices

Clinical Performance Summary

Clinical testing was not completed/is not required to show substantial equivalence.

Conclusions from Testing

PARI Sinus meets performance requirements and raises no new issues of safety or effectiveness.

DEPARTMENT OF HEALTH & HUMAN SERVICES

Public Health Service

Food and Drug Administration
10903 New Hampshire Avenue
Document Control Room –WO66-G609
Silver Spring, MD 20993-0002

Mr. Michael Judge
Director, QA/RA
PARI Respiratory Equipment, Incorporated
2943 Oak Lake Boulevard
Midlothian, Virginia 23112

Re: K092560

MAY - 6 2010

Trade/Device Name: PARI Sinus
Regulation Number: 21 CFR 868.5630
Regulation Name: Nebulizer
Regulatory Class: II
Product Code: CAF
Dated: April 26, 2010
Received: April 30, 2010

Dear Mr. Michael Judge:

We have reviewed your Section 510(k) premarket notification of intent to market the device referenced above and have determined the device is substantially equivalent (for the indications for use stated in the enclosure) to legally marketed predicate devices marketed in interstate commerce prior to May 28, 1976, the enactment date of the Medical Device Amendments, or to devices that have been reclassified in accordance with the provisions of the Federal Food, Drug, and Cosmetic Act (Act) that do not require approval of a premarket approval application (PMA). You may, therefore, market the device, subject to the general controls provisions of the Act. The general controls provisions of the Act include requirements for annual registration, listing of devices, good manufacturing practice, labeling, and prohibitions against misbranding and adulteration. Please note: CDRH does not evaluate information related to contract liability warranties. We remind you, however, that device labeling must be truthful and not misleading.

If your device is classified (see above) into either class II (Special Controls) or class III (PMA), it may be subject to additional controls. Existing major regulations affecting your device can be found in the Code of Federal Regulations, Title 21, Parts 800 to 898. In addition, FDA may publish further announcements concerning your device in the Federal Register.

Please be advised that FDA's issuance of a substantial equivalence determination does not mean that FDA has made a determination that your device complies with other requirements of the Act or any Federal statutes and regulations administered by other Federal agencies. You must comply with all the Act's requirements, including, but not limited to: registration and listing (21 CFR Part 807); labeling (21 CFR Part 801); medical device reporting (reporting of medical device-related adverse events) (21 CFR 803); good manufacturing practice requirements as set forth in the quality systems (QS) regulation (21 CFR Part 820); and if applicable, the electronic product radiation control provisions (Sections 531-542 of the Act); 21 CFR 1000-1050.

If you desire specific advice for your device on our labeling regulation (21 CFR Part 801), please go to http://www.fda.gov/AboutFDA/CentersOffices/CDRH/CDRHOffices/ucm115809.htm for the Center for Devices and Radiological Health's (CDRH's) Office of Compliance. Also, please note the regulation entitled, "Misbranding by reference to premarket notification" (21CFR Part 807.97). For questions regarding the reporting of adverse events under the MDR regulation (21 CFR Part 803), please go to http://www.fda.gov/MedicalDevices/Safety/ReportaProblem/default.htm for the CDRH's Office of Surveillance and Biometrics/Division of Postmarket Surveillance.

You may obtain other general information on your responsibilities under the Act from the Division of Small Manufacturers, International and Consumer Assistance at its toll-free number (800) 638-2041 or (301) 796-7100 or at its Internet address http://www.fda.gov/MedicalDevices/ResourcesforYou/Industry/default.htm.

Sincerely yours,

for

Anthony D. Watson, B.S., M.S., M.B.A.
Director
Division of Anesthesiology, General Hospital,
Infection Control and Dental Devices
Office of Device Evaluation
Center for Devices and
Radiological Health

Enclosure

Indications for Use

510(k) Number (if known): N/A

Device Name: PARI Sinus

Indications for Use:

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Prescription Use XXX (Part 21 CFR 801 Subpart D) AND/OR Over-The-Counter Use _____ (21 CFR 801 Subpart C)

(PLEASE DO NOT WRITE BELOW THIS LINE-CONTINUE ON ANOTHER PAGE OF NEEDED)

Concurrence of CDRH, Office of Device Evaluation (ODE)

(Division Sign-Off)
Division of Anesthesiology, General Hospital
Infection Control, Dental Devices

510(k) Number: K092560

(Posted November 13, 2003)